(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 June 2002 (06.06.2002)

PCT

(10) International Publication Number
WO 02/43591 A2

(51) International Patent Classification[7]: A61B 5/15

(21) International Application Number: PCT/GB01/05181

(22) International Filing Date:
26 November 2001 (26.11.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0028926.4 28 November 2000 (28.11.2000) GB

(71) Applicant *(for all designated States except US)*: **OWEN MUMFORD LIMITED** [GB/GB]; Brook Hill, Woodstock, Oxford OX20 1TU (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MARSHALL, Jeremy** [GB/GB]; 16 Cranham Street, Jericho, Oxford OX2 6DD (GB).

(74) Agents: **LAINE, Simon, James** et al.; Wynne-Jones, Laine & James, 22 Rodney Road, Cheltenham, Gloucestershire GL5O 1JJ (GB).

(81) Designated States *(national)*: JP, US.

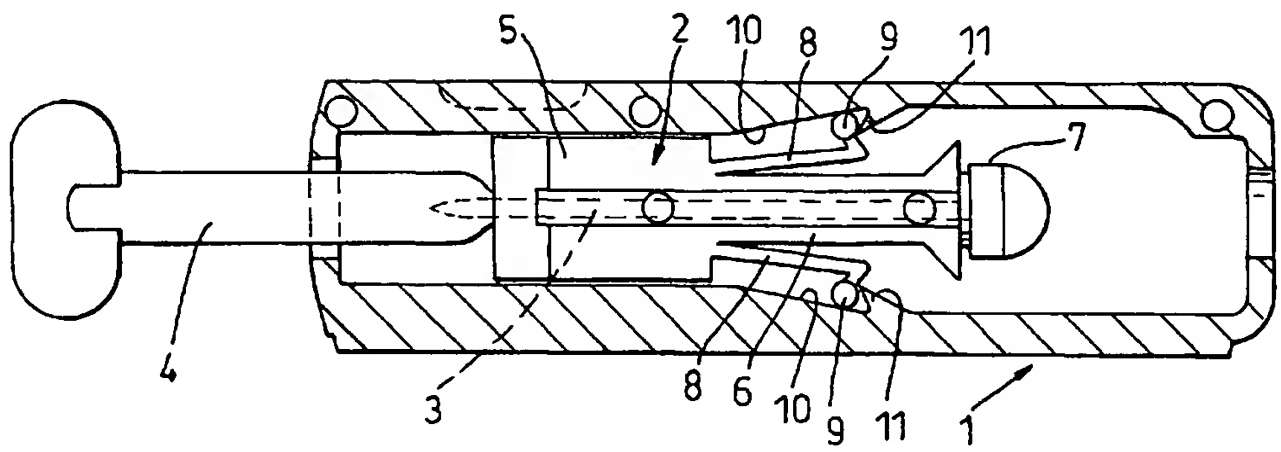
(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVEMENTS RELATING TO SKIN PRICKERS



(57) Abstract: A skin pricker for blood sampling has a barrel (1) housing a lancet (2) which can be pushed back against a spring to a primed condition, by an elongate cap (4) over its needle tip there to be held by a trigger. The cap (4) is removed by twist and pull action. The lancet body (5, 6) has integrally formed spring arms (8, 18) extending rearwardly and alongside, and when the lancet (2) is fired these are momentarily flexed inwardly as their tips (9, 19) snap past abutments (11) within the barrel (1). These act as ratchets, providing a first defence against re-priming of the pricker. If that first defence is overcome by a substantial rearward force on the lancet, the spring arms rearward pointing V's which wedge between the abutments (11) and the lancet body (6). The cap (4) may have a weakness (20, 21) leaving it rigid enough for the initial priming but which causes it to buckle if used to try to overcome the ratchet.

WO 02/43591 A2

Improvements relating to skin prickers

This invention relates to skin prickers. It is a development of that described in EP-B-0634000, and is concerned with ensuring that the lancet, once fired, cannot be pushed back via the needle tip aperture, re-cocked and re-fired.

According to one aspect of the present invention there is provided a disposable pricker comprising an elongate housing with a spring-loaded, longitudinally movable lancet carried therein, the lancet tip normally being within the housing, a trigger mechanism to retain the lancet in a fully retracted position energising the spring means and actuable to release or fire the lancet to cause the tip to have a momentary position projecting from the forward end of the housing, and means for preventing repeated use including a spring finger extending rearwardly from the lancet alongside but spaced from the body thereof, and an abutment on the inside of the housing past which the tip of the finger cap snap during forward motion of the lancet, any attempt to push the lancet back with a greater than predetermined force after firing causing the finger, with its tip arrested by the abutment, to buckle into a rearward pointing V that wedges between the abutment and the body of the lancet.

Preferably, the lancet is symmetrical, with two fingers on opposite sides thereof. The housing will then have two opposed abutments, and these may be shaped as

barbs pointing inwards and forwards.

In one form the or each finger inclines outwardly from the lancet body as well as extending rearwardly.

Alternatively the or each finger may be generally parallel to and spaced from the adjacent part of the body of the lancet but with its tip flaring outwardly.

The needle tip may initially be protected by an elongate cap by which the lancet can be pushed back to the fully retracted position from an initial pre-fired position with the or each finger tip immediately to the rear of the associated abutment. For preventing this cap being usable to force the lancet back beyond the position at which it is held by the abutment(s) after firing, the elongate cap preferably has a weakness that is not significant when the cap is used for retracting the lancet from said initial position. However, it will cause the cap to deform if the cap is subjected to excessive axial compression, as when being used to try to push the lancet back after firing. This weakness is conveniently by way of a local reduction of the cross-section of the elongate cap, the deformation being buckling.

This cap with a weakness need not be confined to the lancet and pricker defined above.

Therefore, according to another aspect of the present invention there is provided a lancet for a skin pricker, the lancet having a plastics body integrally moulded with a breakaway cap around a needle, the cap having an elongate

stem aligned with the needle and with an end encasing the needle tip, the latter being exposed when the cap is removed, wherein the stem has a zone of weakness whereby longitudinal compression of the cap above a predetermined level will cause the stem to buckle.

The zone of weakness is conveniently created by at least one notch indented into the stem, and preferably there will be two notches on opposite sides and mutually offset longitudinally of the stem. Other possibilities are a transverse bore through the stem, or the latter being formed with a neck.

For a better understanding of the invention, some embodiments will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is an axial section of a skin pricker after its lancet has been fired,

Figure 2 is a similar section showing an attempt to retract the lancet after firing,

Figure 3 is an axial section of another skin pricker before its lancet is fired,

Figure 4 is a similar section showing the lancet of Figure 3 after firing,

Figure 5 is a side view of a skin pricker with a safety cap for the needle tip, and

Figure 6 is a similar side view showing the cap being used to try to retract a fired lancet.

The device of Figures 1 and 2 has a barrel 1 of two

halves joined at a longitudinal split to hold a lancet 2. The lancet has a plastics body encasing a needle 3 whose tip is initially embedded in a twist-off elongate cap 4 moulded integrally with the body. The cap serves the same purpose as that in EP-B-0634000. The spring that drives the lancet forwards and the trigger that releases it are not shown for simplicity.

The lancet body has a large head 5 non-rotatably guided in the forward part of the barrel. A stem 6 extends rearwardly from the head terminating in a formation 7 that locates the leading end of the spring. At opposite sides of the stem fingers 8 lead outwardly and rearwardly from the roots of the shoulders at the transition between the head 5 and the stem 6. They terminate in enlargements 9. Being integrally moulded with the plastics body, they are resiliently flexible and can act as springs.

At about its mid-length the interior of the barrel 1 widens towards the rear at opposite sides in gradual slopes 10 terminating in inwardly and forwardly angled barbs 11.

Initially, with the spring relaxed, the enlargements 9 are behind the barbs 11. The cap 4 is pressed to retract the lancet, and the device is then cocked. The cap is twisted off and the device is applied and fired. The thrust of the spring urges the lancet forwards and the fingers 8 flex inwards as the enlargements 9 snap past the barbs 11, just before the needle tip momentarily emerges from the forward end of the barrel. As the over extended

spring retracts, the enlargements 9 slide along the slopes 10 until they engage the hooks formed by the barbs 11. There is effectively a ratchet mechanism.

This is the position shown in Figure 1, with the cap 4 pushed back in with a view to restoring the device to its cocked condition.

However, if the cap is pushed further, while the main body of the lancet will move, at least initially, the fingers 8 are trapped. They will then buckle as shown in Figure 2 to form rearward pointing Vs, and thus wedges that will jam between the barbs 11 and the stem 6. The enlargements 9 ensure that the ends of the fingers 8 do not flip clear of the barbs.

Thus the lancet is arrested and immobilised before the cocked position is reached, and re-firing is prevented.

The device of Figures 3 and 4 is similar in many respects to that of Figures 1 and 2, and corresponding parts are similarly referenced.

The significant difference lies in the spring fingers, now referenced 18. They extend rearwardly from the tips of the shoulders at the transition between the head 5 and the stem 6, and they normally lie parallel to and spaced from that stem. They terminate in outwardly flared tips 19.

The ratchet operation is similar to that described. When the lancet is fired, towards the end of its forward movement the tips 19 snap past the barbs 11, momentarily flexing the arms 18 inwards. The bounce back of the lancet

leaves the tips 19 loosely engaging those barbs. Any rearward force on the lancet enhances that engagement, and rearward movement of the lancet is resisted by the arms 18, which remain straight under light longitudinal compression. However, once the rearward force reaches a certain level they begin to bend and the arms flex inwards rather than outwards, as shown in broken lines in Figure 4, by virtue of the engagement of the tips by the barbs outside the main length of the arms. The tips 19 will spear outwardly as well as rearwardly into the acute angles of the barbs 11 and will therefore be less likely to jump those barbs. Further force will cause the arms to buckle and wedge as in the previous embodiment.

These are necessarily small devices and the size of the barbs 11 and the arms that engage them are correspondingly small. While they will operate as described when moderate rearward force is applied to the lancet after firing, a really determined push could break down the engagement at the barbs 11 and re-cock the device. The obvious instrument for applying this push is the elongate cap 4, removed but perhaps not discarded immediately prior to use.

As a further safety measure, applicable not just to the embodiments described, the cap 4 may be constructed to render it useless for retracting the lancet after firing. In the example of Figures 5 and 6 two notches 20 and 21 are formed in opposite sides at slightly different axial

positions around the mid-length of the stem of the cap, making a zig-zag. The cap 4 will be rigid enough for the initial cocking of the device against the spring, but if the lancet is held by the barbs 11, the cap will buckle as shown in Figure 6 before the barbs 11 or the tips of the arms 8 or 18 give way.

Another way of weakening the cap, which may be preferred, is simply to have a transverse bore through it at around the mid-length. Alternatively, just one notch may suffice, or it may be formed with a neck.

In the embodiments described, the lancet is symmetrical, with spring arms 8 or 18 on opposite sides. While this is preferred, it would be possible to construct and guide the lancet so that only one arm would suffice.

CLAIMS

1. A disposable pricker comprising an elongate housing with a spring-loaded, longitudinally movable lancet carried therein, the lancet tip normally being within the housing, a trigger mechanism to retain the lancet in a fully retracted position energising the spring means and actuable to release or fire the lancet to cause the tip to have a momentary position projecting from the forward end of the housing, and means for preventing repeated use including a spring finger extending rearwardly from the lancet alongside but spaced from the body thereof, and an abutment on the inside of the housing past which the tip of the finger cap snap during forward motion of the lancet, any attempt to push the lancet back with a greater than predetermined force after firing causing the finger, with its tip arrested by the abutment, to buckle into a rearward pointing V that wedges between the abutment and the body of the lancet.

2. A disposable pricker as claimed in Claim 1, wherein the lancet is symmetrical, with two fingers on opposite sides thereof, and the housing has two opposed abutments.

3. A disposable pricker as claimed in Claim 1 or 2, wherein the or each abutment is shaped as a barb, pointing inwards and forwards.

4. A disposable pricker as claimed in Claim 1, 2 or 3, wherein the or each finger inclines outwardly from the lancet body as well as extending rearwardly.

5. A disposable pricker as claimed in Claim 1, 2 or 3, wherein the or each finger is generally parallel to and spaced from the adjacent part of the body of the lancet but with its tip flaring outwardly.

6. A disposable pricker as claimed in any preceding claim, wherein the needle tip is initially protected by an elongate cap by which the lancet can be pushed back to the fully retracted position from an initial pre-fired position with the or each finger tip immediately to the rear of the associated abutment.

7. A disposable pricker as claimed in Claim 6, wherein the elongate cap has a weakness that is not significant when the cap is used for retracting the lancet from said initial position but which causes the cap to deform if used to try to push the lancet back after firing.

8. A disposable pricker as claimed in Claim 7, wherein the weakness is by way of a local reduction of the cross-section of the elongate cap, the deformation being buckling.

9. A lancet for a skin pricker, the lancet having a plastics body integrally moulded with a breakaway cap around a needle, the cap having an elongate stem aligned with the needle and with an end encasing the needle tip, the latter being exposed when the cap is removed, wherein the stem has a zone of weakness whereby longitudinal compression of the cap above a predetermined level will cause the stem to buckle.

10. A lancet as claimed in Claim 9, wherein the zone of weakness is created by at least one notch indented into the stem.

11. A lancet as claimed in Claim 10, wherein there are two notches on opposite sides and mutually offset longitudinally of the stem.

12. A lancet as claimed in Claim 9, wherein the zone of weakness is created by a transverse bore through the stem.

13. A lancet as claimed in Claim 9, wherein the zone of weakness is created by a neck in the stem.

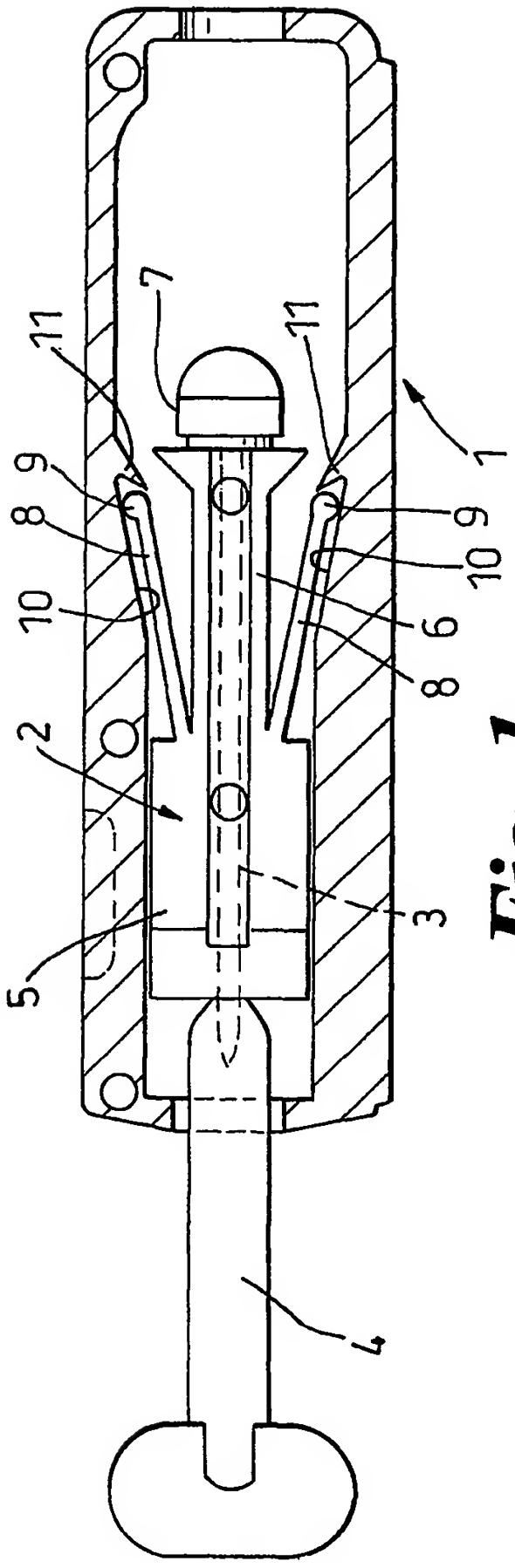


Fig. 1

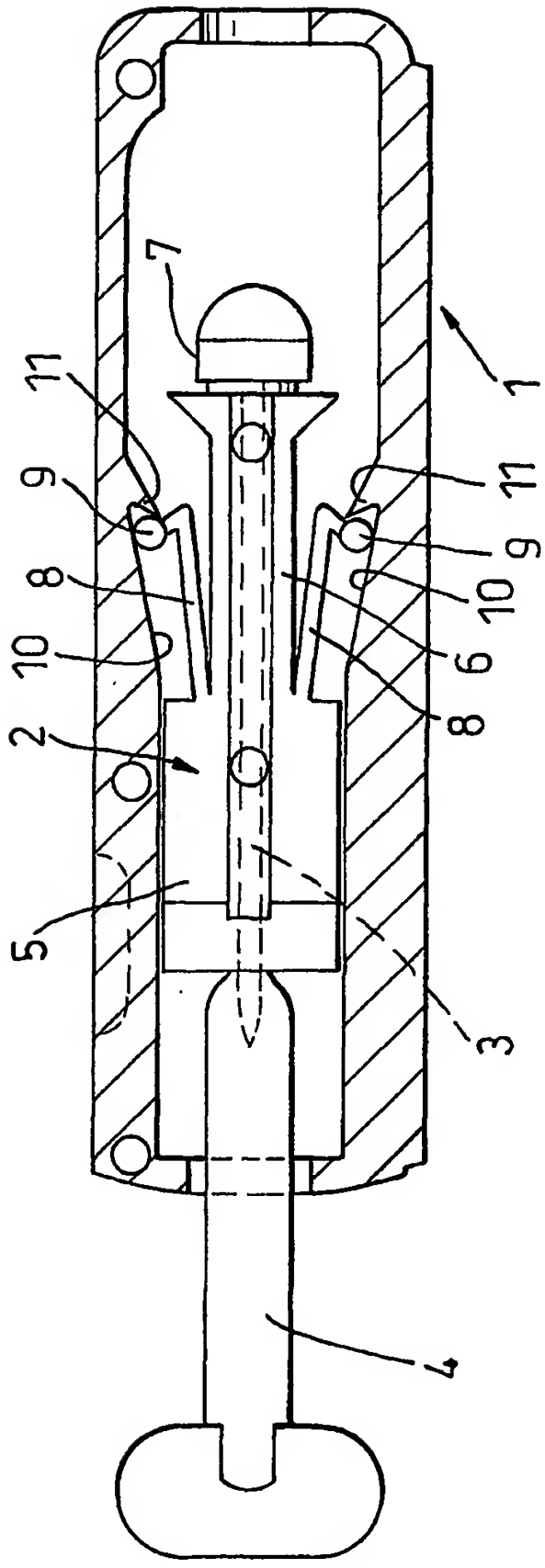


Fig. 2

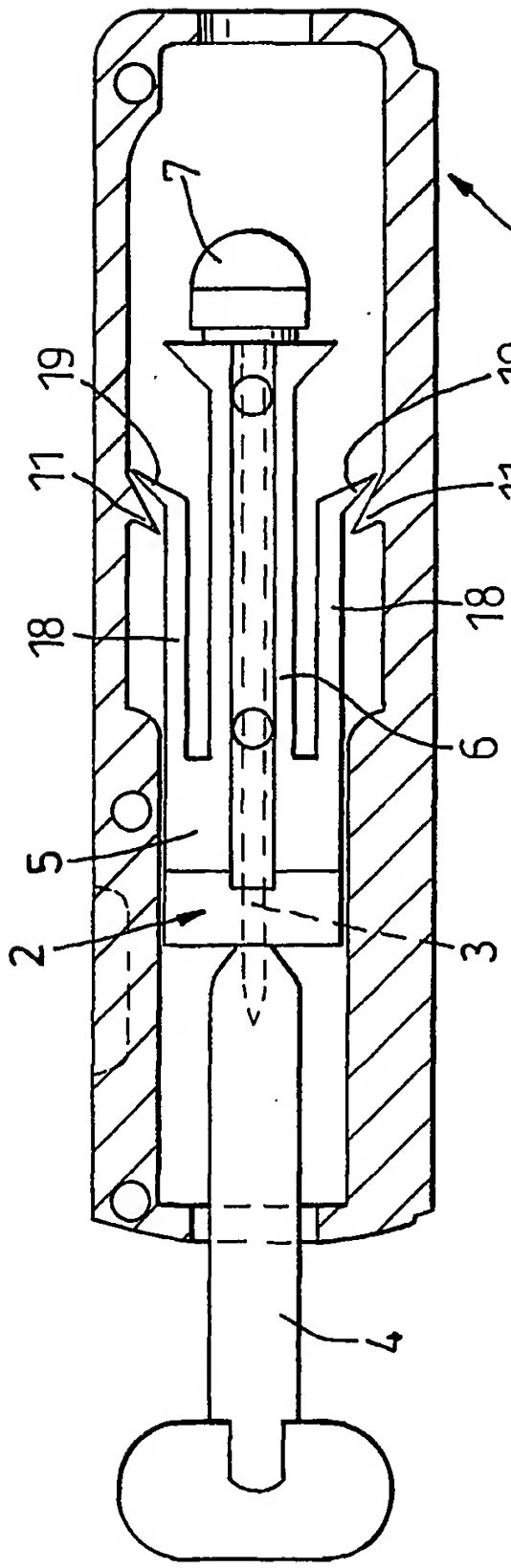


Fig. 3

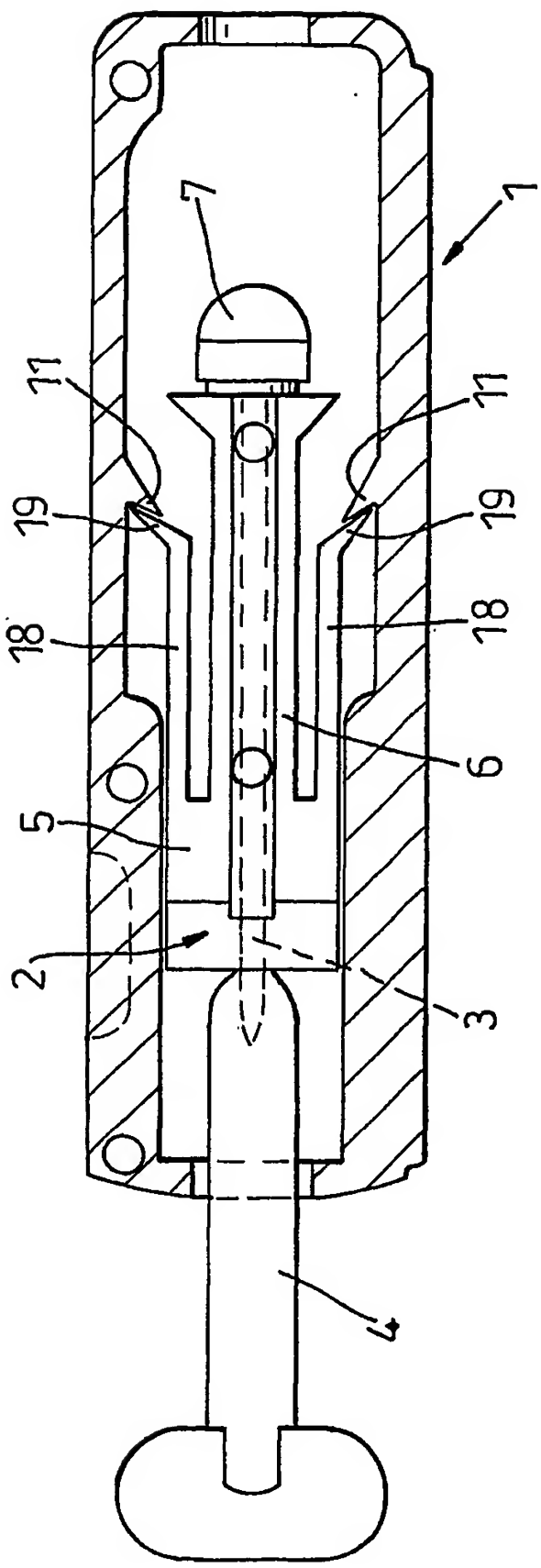


Fig. 4

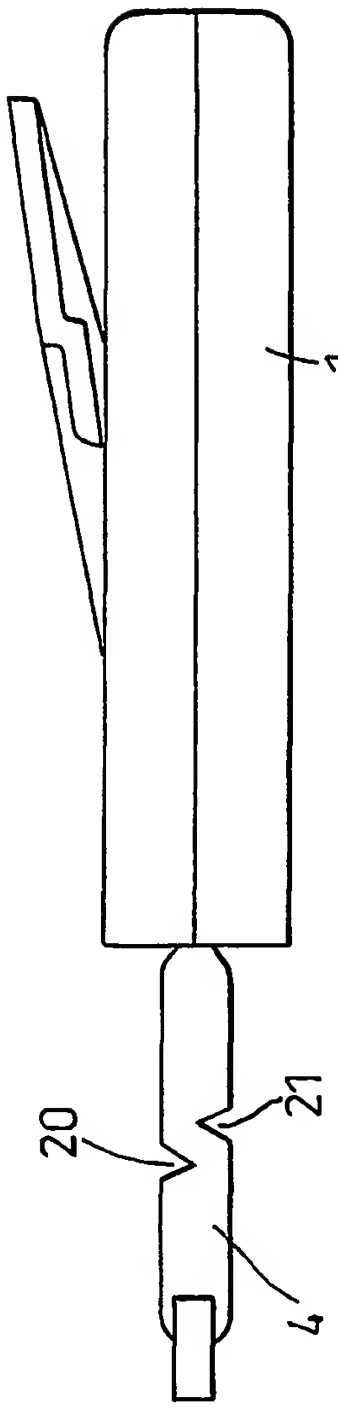


Fig. 5

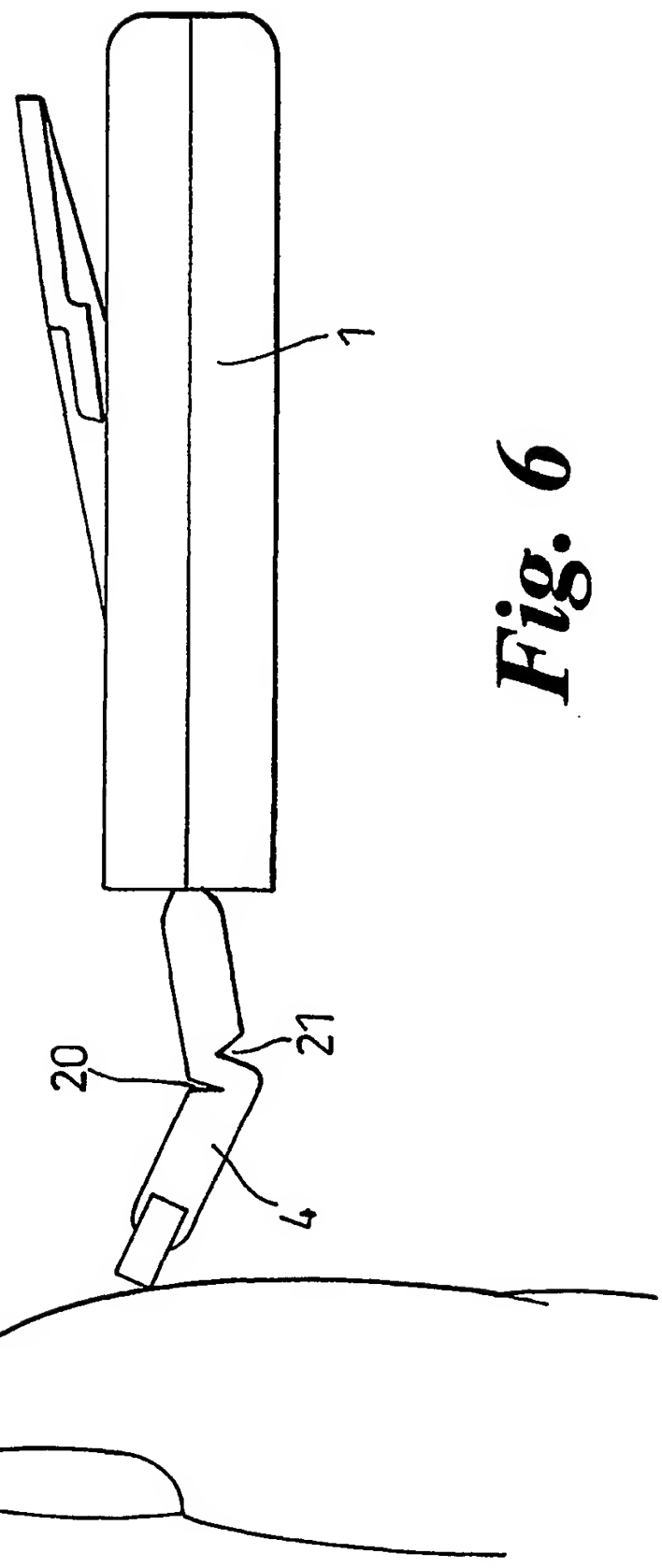


Fig. 6

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 June 2002 (06.06.2002)

PCT

(10) International Publication Number
WO 02/043591 A3

(51) International Patent Classification[7]: A61B 5/15

(21) International Application Number: PCT/GB01/05181

(22) International Filing Date:
26 November 2001 (26.11.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0028926.4 28 November 2000 (28.11.2000) GB

(71) Applicant *(for all designated States except US)*: **OWEN MUMFORD LIMITED** [GB/GB]; Brook Hill, Woodstock, Oxford OX20 1TU (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MARSHALL, Jeremy** [GB/GB]; 16 Cranham Street, Jericho, Oxford OX2 6DD (GB).

(74) Agents: **LAINE, Simon, James** et al.; Wynne-Jones, Laine & James, 22 Rodney Road, Cheltenham, Gloucestershire GL50 1JJ (GB).

(81) Designated States *(national)*: JP, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

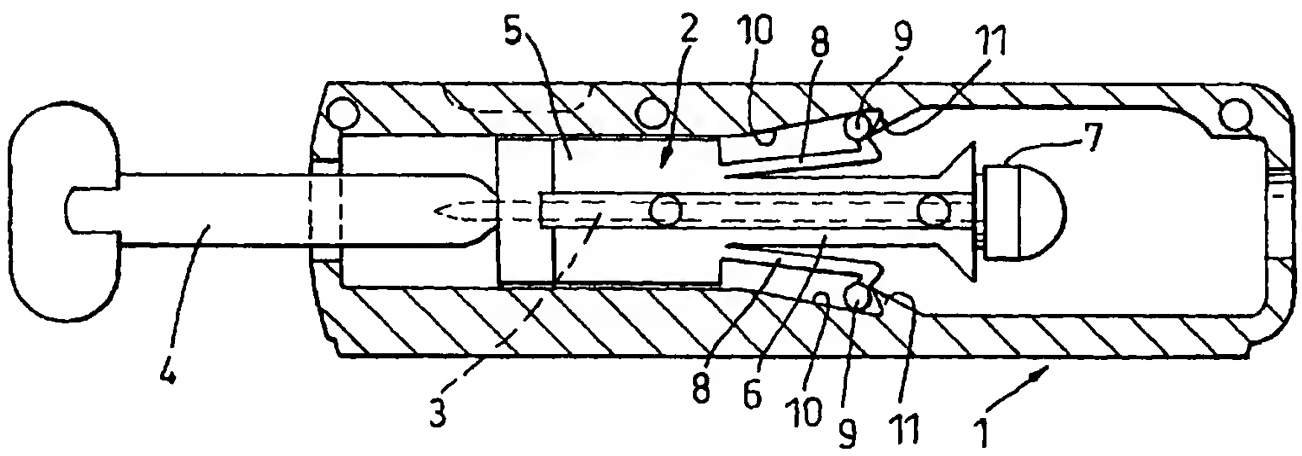
Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv)) for US only*

Published:
— *with international search report*

(88) Date of publication of the international search report:
6 September 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVEMENTS RELATING TO SKIN PRICKERS



(57) Abstract: A skin pricker for blood sampling has a barrel (1) housing a lancet (2) which can be pushed back against a spring to a primed condition, by an elongate cap (4) over its needle tip there to be held by a trigger. The cap (4) is removed by twist and pull action. The lancet body (5, 6) has integrally formed spring arms (8, 18) extending rearwardly and alongside, and when the lancet (2) is fired these are momentarily flexed inwardly as their tips (9, 19) snap past abutments (11) within the barrel (1). These act as ratchets, providing a first defence against re-priming of the pricker. If that first defence is overcome by a substantial rearward force on the lancet, the spring arms rearward pointing V's which wedge between the abutments (11) and the lancet body (6). The cap (4) may have a weakness (20, 21) leaving it rigid enough for the initial priming but which causes it to buckle if used to try to overcome the ratchet.

WO 02/043591 A3

INTERNATIONAL SEARCH REPORT

International Application No
PCT GB 01/05181

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 487 748 A (MARSHALL JEREMY ET AL) 30 January 1996 (1996-01-30) cited in the application the whole document ---	1,6
A	US 6 136 013 A (MUMFORD ERNEST JOHN ET AL) 24 October 2000 (2000-10-24) column 2, line 11 -column 3, line 3; figures ---	1,3,4,6
A	US 5 439 473 A (JORGENSEN PETER) 8 August 1995 (1995-08-08) column 2, line 19 -column 4, line 19; figures 1-3 ---	1-3,6

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 May 2002	05.06.02

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Dhervé, G

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
P GB 01/05181

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 741 288 A (RIFE DOUGLAS EARL) 21 April 1998 (1998-04-21) column 6, line 17-28 column 10, line 61 -column 11, line 5 figures 22,24	1
X	US 5 554 166 A (ARGAUER HERBERT ET AL) 10 September 1996 (1996-09-10) column 6, line 1-17; figure 2	9
A	DE 197 18 081 A (BOEHRINGER MANNHEIM GMBH) 5 November 1998 (1998-11-05) column 5, line 61 -column 6, line 19; figures	9-11,13
A	US 5 707 384 A (KIM INHWAN) 13 January 1998 (1998-01-13) column 3, line 36-44; figure 3	9

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 01/05181

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ *The additional search fees were accompanied by the applicant's protest.*

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-8

   A disposable pricker comprising means for preventing repeated use.

2. Claims: 9-13

   A lancet for skin pricker comprising a cap with a stem having a zone of weakness.

INTERNATIONAL SEARCH REPORT

International Application No
F /GB 01/05181

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5487748 A	30-01-1996	AU 3895493 A	08-11-1993
		BR 9306161 A	13-01-1998
		CA 2132329 A1	14-10-1993
		DE 69304320 D1	02-10-1996
		DE 69304320 T2	30-01-1997
		DK 634000 T3	24-02-1997
		EP 0634000 A1	18-01-1995
		WO 9319671 A1	14-10-1993
		JP 2635823 B2	30-07-1997
		JP 7505307 T	15-06-1995
		KR 151748 B1	01-10-1998
		RU 2114559 C1	10-07-1998
US 6136013 A	24-10-2000	EP 0975938 A1	02-02-2000
		WO 9811821 A1	26-03-1998
		JP 2001507250 T	05-06-2001
US 5439473 A	08-08-1995	NONE	
US 5741288 A	21-04-1998	NONE	
US 5554166 A	10-09-1996	DE 4320463 A1	22-12-1994
		AT 206299 T	15-10-2001
		CA 2125605 A1	22-12-1994
		DE 59409886 D1	08-11-2001
		EP 0630609 A2	28-12-1994
		ES 2163416 T3	01-02-2002
		JP 2598229 B2	09-04-1997
		JP 7016218 A	20-01-1995
		SG 46604 A1	20-02-1998
DE 19718081 A	05-11-1998	DE 19718081 A1	05-11-1998
		AU 7432398 A	24-11-1998
		WO 9848695 A1	05-11-1998
		EP 0987983 A1	29-03-2000
US 5707384 A	13-01-1998	CA 2178871 A1	27-12-1996
		JP 9182736 A	15-07-1997